REMARKS

By this Amendment, Applicants have amended claims 10 and 32 and have canceled claims 42-47 and 64, without prejudice or disclaimer of the subject matter thereof. Accordingly, claims 1-41 and 48-63 are pending in this application. No new matter has been added to this application by this Reply.

In the outstanding Office Action, claims 1-61 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ambrisco et al. (U.S. Patent No. 6,007,557) in view of Ding et al. (U.S. Patent No. 5,879,697), and also as unpatentable over Daniel et al. (U.S. Patent No. 6,171,327) in view of Thompson et al. (U.S. Patent No. 5,834,449) and further in view of Ding.

Applicants respectfully traverse the rejections of independent claim 1 under 35 U.S.C. § 103(a) in view of Ambrisco and Ding, and Daniel, Thompson, and Ding. In particular, Applicants submit it is improper to apply Ding in rejecting independent claim 1 because Ding is not analogous art. In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." M.P.E.P. § 2141.01(a) citing *In re Oetiker*, 977 F.2d 1443, 1446.

The invention of claim 1 relates to a collapsible filter element for a transcatheter embolic protection device including, *inter alia*, a collapsible filter body, a proximal inlet, and a distal outlet. The filter body is at least partially of a laminate construction comprising a membrane coated with a coating which is biocompatible, and the thickness of the coating is from 4% to 40% of the thickness of the membrane to

enhance the mechanical characteristics of the filter body. In particular this thickness percentage enables the filter body to have a low profile but still retain good memory characteristics, as explained on page 23, line 28, to page 24, line 2, of the patent specification.

The aspects of low profile and memory characteristics are particularly important in the case of a filter element for a transcatheter embolic protection device. For example, a low profile filter element may be more easily exchanged through a vasculature. In addition, the memory characteristics ensure that the filter element will expand fully when deployed in a vasculature to capture emboli passing through the vasculature.

Ding relates to the field of drug-releasing coatings on medical devices. Ding includes a list of elements suitable for use with the disclosed drug-releasing coatings at column 4, lines 58-68, of the patent. Missing from the list is a collapsible filter element for a transcatheter embolic protection device as recited in independent claim 1 of the present invention. The thicknesses of the drug-releasing coatings disclosed in Ding are chosen based on the desired drug release rate and a drug release profile. See column 9, lines 1-6, of Ding.

Applicants submit that one of ordinary skill in the art would not recognize Ding as being in the field of applicant's endeavor. As noted above, Ding relates particularly to the use of a drug-releasing type coatings. The filter of independent claim 1 does not recite a drug-releasing coating, but rather a coating that enables a filter body to have a low profile and good memory characteristics. In addition, Ding does not disclose such a drug-releasing type of coating in association with a collapsible filter elements for

transcatheter embolic protection devices. For these reasons, Applicants submit that Ding is not within the field of applicant's endeavor.

In addition, Applicants submit that Ding is not reasonably pertinent to the particular problem with which the Applicants were concerned. As noted above, Ding relates to the problem of forming a coating with appropriate thickness to obtain a desired drug release rate and drug release profile. This is in contrast to the problems associated with the claimed collapsible filter element for a transcatheter embolic protection device relating to enabling a filter body to have a low profile but still retain good memory characteristics.

In view the above, Applicants submit that Ding is not analogous art and therefore request that the rejection of claim 1 in view of Ambrisco and Ding, and Daniel, Thompson, and Ding be withdrawn. In addition, Applicants also request that the rejections of claims 2-31 and 48-62 be withdrawn for the reasons detailed above and based on their dependence from claim 1.

Applicants also request withdrawal of the 35 U.S.C. § 103(a) rejection of independent claim 32 in view of Ambrisco and Ding, and Daniel, Thompson, and Ding. Claim 32 has been amended to recite the feature of the filter support frame which supports the filter body in the expanded position. In view of this amendment, Applicants submit that the claimed "filter body having regions of at least one of varying hardness and stiffness resulting at least in part from a laminate construction of at least one of the regions" cannot be interpreted as including varying stiffness based on the inclusion of the filter support frame. Accordingly, Applicants traverse the position provided in the outstanding Office Action that

> In regard to different stiffness of filter sections, Ambrisco disclose[s] filter elements having different stiffness. [F]or example in figure 35-36 of Ambrisco, the different stiffness between sections [ ] having expanding frame 313 and sections (310) that do not have the expanding frame (313)"

(Office Action at page 3, lines 9-12.)

In Fig. 35 of Ambrisco, a filter apparatus 200 is disclosed having a plurality of filter mesh segments 310. Each segment 310 has an apex 311, a base 312, two sides 313, 314 and a mesh 80. Together the apex 311, base 312 and sides 313, 314 of all of the segments 310 appear to function as an overall support frame to support all of the meshes 80. However there is no disclosure in Ambrisco of the meshes 80 having a laminate construction, or of the meshes 80 having regions of varying hardness or stiffness. Thus, Applicants submit that Ambrisco does not disclose the filter body with regions of at least one of varying hardness and stiffness as recited in independent claim 32.

The remaining prior art to Ding, Daniel, and Thompson similarly fail to disclose or suggest the claimed collapsible filter element having a filter body including regions of at least one of varying hardness and stiffness resulting at least in part from a laminate construction of at least one of the regions, as recited in independent claim 32. For at least this reason, Applicants submit that the cited art to Ambrisco, Ding, Daniel, and Thompson all fail to disclose or suggest each and every aspect of independent claim 32. Accordingly, Applicants request that the prior art rejections applied against claim 32 be withdrawn. Applicants also request withdrawal of the prior art rejections against claims 33-41 and 63 at least for the reasons detailed above with respect to claim 32 and based on their dependency from claim 32.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Reply and charge any additional required fees with the exception of the filing fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 18, 2005

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